Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence

Edinburgh International Conference 2 – 4 June 2014: Better clinical guidelines, better healthcare decisions

The first International Conference of the DECIDE project took place at the Royal College of Physicians of Edinburgh, Scotland from the 2nd to the 4th of June 2014 with the aims of disseminating the results of the project, providing training through specific workshops and promoting improved methods of grading evidence and strength of recommendations.

More than 250 delegates coming from all over the world took part to the works of the conference, mainly organized around a series of workshop sessions aimed at presenting some of the interactive tools developed (ISOF tables, EtD frameworks, MAGIC platform, GET-IT).

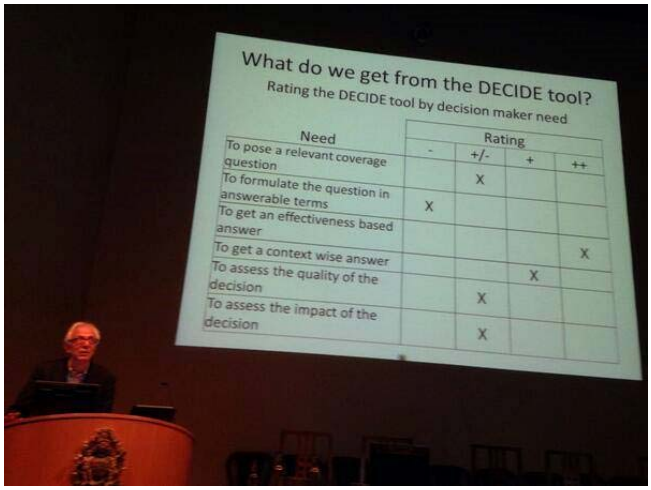
Originally this Conference should have been held at the end of the project (December 2015), however the DECIDE Consortium considered that having the opportunity of disseminating and collecting feedbacks about the activity and the tools developed at mid-term could have represented an added value for the completion of the DECIDE Project's deliverables.

In this view the conference was organized to give the opportunity to different types of stakeholders to bring and share experiences and suggestions helpful in refining the DECIDE tools and in making them better applicable in the real life for different target audiences.

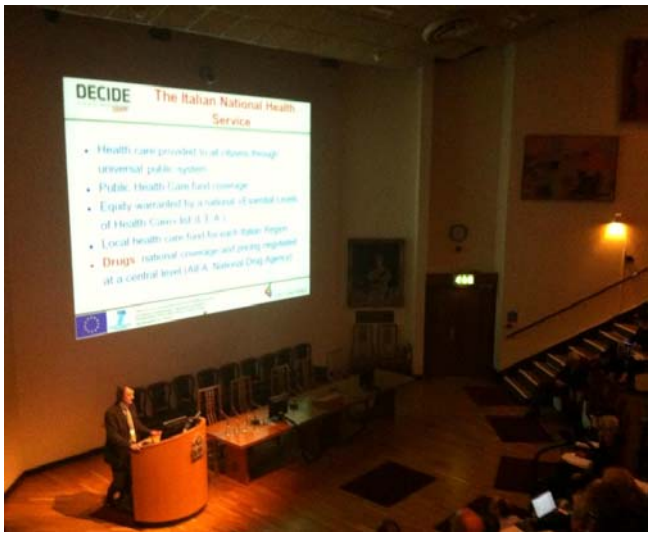
From the works of the first day emerged the importance of developing evidence-based guidelines for patients who have comorbidities (Bruce Guthrie), the need of including patients' decision aids in the *evidence-to-decision* process (Peter Olaf Vandvik), the use of priority criteria (based on three aspects: change, time and resources) when developing clinical guidelines (Melissa Browers).

The second day of the conference was initially dedicated to the ways of communicating evidence-based decisions via the media and other organizations. Here again the patient's point of view should be taken into account, especially in the ways evidence is presented (through blogs, websites and other social media tools) and described (plain language, accessible to everyone) (SIGN working group). A recent study (Bastian 2011) in fact pointed out that less than 10% of the evidence produced is considered interesting by patients.

One of the plenary sessions of the second day was dedicated to the application of the DECIDE tools to coverage decisions. This session was introduced and coordinated by Marina Davoli, head of the Department of Epidemiology of Lazio Regional Health Service, which is responsible for the Work Package 2 of the DECIDE Project and it was focused on the different factors involved in taking coverage decision and the usefulness and potentiality of the DECIDE tool in this field analysed by two different perspectives: the policy maker's and the methodologist's one.



From a policy-maker perspective (Carlo Saitto) it is of fundamental importance the act of posing relevant coverage questions, having in mind that public health priorities do not necessarily correspond to those called by clinicians and patients. Research questions need then to be formulated in answerable terms, using well known models (i.e. PICO model), and be timely answered. From a methodologist perspective the DECIDE tools are pretty useful in getting answers based on the evidence and context-wise, as stated by Francesco Nonino when presenting the new recommendations on incretins for the treatment of diabetes.



However still there is a lack of reliable criteria to help policy-makers assessing the quality and the impact of the decision taken.

Another plenary session during the second day, coordinated by Patrick Bossuyt (work package 3), was dedicated to shared decision making and recommendations about medical tests. In particular some experiences of developing and communicating public health recommendations were discussed (i.e. colorectal cancer screening recommendations in the Netherlands and evidence-based diagnostic decisions in Scotland).

The presentations of the last day of the conference regarded the use of the *evidence to recommendation* and the *evidence to decision* frameworks in developing guidelines and public health policies respectively. The main points emerged during the last session were: the added value of a collaboration among institutions; the importance of a transparent method and the need of a structured process that allows to take health care decisions in a short period of time.

The conference was closed by a round table chaired by Andy Oxman (WP5 leader) which aimed at summing up all the themes emerged during the three days of conference trying to highlight future developments for the DECIDE Project and guidelines in general. Participants to the discussion were Jako Burgers from Dutch College of General Practitioners, Roberta James from SIGN, Stephen Pilling from NICE/London University College and David Tovey from the Cochrane Editorial Unit.

WP2' specific activities during the Edinburgh Conference

Our work package (WP2) was responsible for the organization of a workshop about the application of the DECIDE tool to decisions of disinvestment. The workshop resulted from a collaboration with an Italian research group (Italian Cochrane Network and Emilia Romagna Health Care Agency) involved in a project (Disinvestment Project) aimed at identifying the so called low-clinical-value interventions: interventions that are routinely used, but not supported by evidence of efficacy. The main objective of the workshop was to collect feedbacks and suggestions about how to adapt the DECIDE tool, originally developed to help policymakers in taking coverage decisions, for a slightly different purpose: help them in taking disinvestment decisions. The participants had the opportunity to examine a practical example of application of the framework to one of the low-clinical-value intervention identified by the Disinvestment Project: opportunistic screening with PSA for prostate cancer in asymptomatic men. The discussion and suggestions received can be summarized in three main points:

- *Rationale for disinvesting*: an intervention could be taken into account for disinvestment if there is no evidence of its efficacy and if it has an economic impact on the budget available. The framework should be ri-structured in a way that puts in first place these two information that should be conditional for proceeding in the disinvestment decision;
- *Implementation strategy*: the framework should include information on how to put into action the disinvestment decision, i.e. communication to patients and professionals (shared-decision making strategies), regulatory policies involved, proposed alternatives, monitor the impact of the decision, etc…
- *Use of the framework*: the framework could be a good way to compare different potential low-value interventions eligible for disinvestment.

WP2 activity was also presented during the conference through 4 posters: two of them were about the development of the Evidence to Coverage Decision framework (EtCD) and its dissemination and use respectively and other two focused on two experiences of practical use of the EtCD on specific topics like medical devices and vaccinations.

For more information about the DECIDE Project and the Edinburgh Conference please visit the website:

http://www.decide-collaboration.eu

DECIDE GRADE Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence

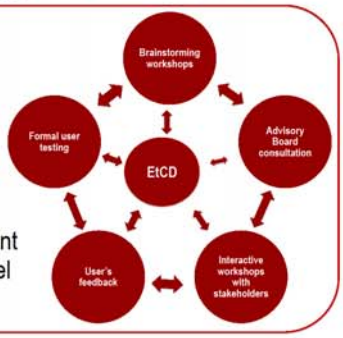
Work Package 2

Policymaker and manager focussed strategies for communicating evidence-based recommendations

Going from evidence to coverage decision

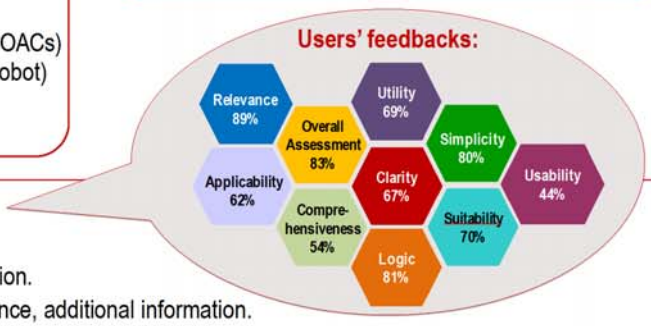
Objective: Development of *tools* and *strategies* targeted to WP2's audience: policy makers, managers and their support staff with responsibility for making coverage decisions. These coverage decisions are defined as decisions by third party payers (public or private health insurers) about whether and how much to pay for drugs, tests, devices or services and under what conditions and can take place at national and/or regional level depending on the type of interventions.

Methods: The initial development of an optimal presentation format was based on the work of the GRADE working group.
The **development process** includes different strategies used in parallel and iteratively.



Results

- 7 Frameworks developed:
  - 3 on drugs (bevacizumab+Paclitaxel , Palivizumab, NOACs)
  - 3 on high cost technologies (MRI, DUS, Da Vinci Robot)
  - 1 on device (Inferior vena cava filter)
- 6 National and International workshops organised



Evidence to Coverage Decision Framework (EtCD)

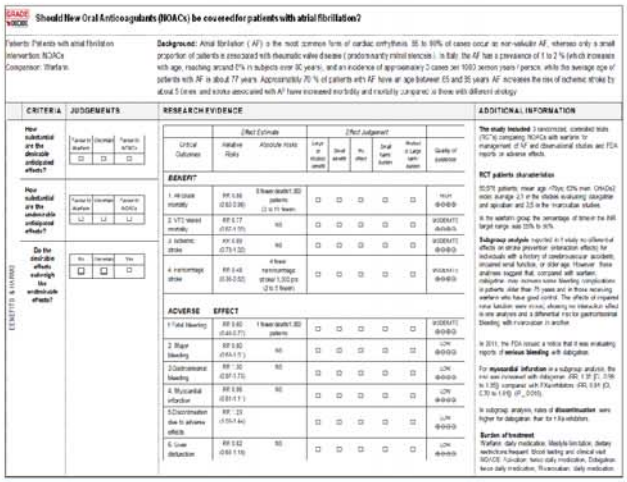
The EtCD is structured in 3 sections:

Section 1: clinical question, PICO, background information.

Section 2: domains, criteria, judgement, research evidence, additional information.

Section 3: balance between desirable and undesirable consequences, decision, restrictions, justification and implementation considerations.

Domain	Criteria
Problem	Is the problem a priority?
Value	Is there important uncertainty about how much people value the main outcomes?
Certainty of the evidence	What is the overall certainty of the evidence of effects?
Benefits & Harms	How substantial are the desirable anticipated effects? How substantial are the undesirable anticipated effects? Do the desirable effects outweigh the undesirable effects?
Resource use	How large are the resource requirements? How large is the incremental cost relative to the net benefit?
Equity	What would be the impact on health inequities?
Acceptability	Is the option acceptable to key stakeholders?
Feasibility	Is the option feasible to implement?


Should New Oral Anticoagulants (NOACs) be covered for patients with atrial fibrillation?

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WP2 Group: Laura Amato, Luciana Ballini, Massimo Brunetti, Roberto D'Amico, Marina Davoli, Luca De Fiore, Rossana De Palma, Eliana Ferroni, Marien Gonzalez Lorenzo, Nicola Magrini, Lorenzo Moja, Francesco Nonino, Salvatore Panico, Donato Papini, Elena Parmelli, Vanna Pistotti, Silvia Pregno, Carlo Saitto, Gianni Virgili, Gustavo Zanoli.

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WP2 Dissemination Activity

National and International Workshops

6 interactive workshops:
- Madrid - Spain
- Quebec City - Canada
- Udine, Rome, Bari and Naples - Italy

A total of 250 participants.

Presentations at Meetings and Conferences

GRADE DECIDE

Evidence to Coverage Decision Framework (EtCD)

Collaboration with Regional Commissions

The Commission for the Drug Approval of the Lazio Region in Italy is using the EtCD framework for its activity.

An example is the EtCD on new oral anticoagulants for atrial fibrillation.

Integration in HTA Reports

Using the framework as a summary appendix for HTA reports: a pilot example is in preparation for an HTA on Transcatheter Aortic Valve Implant (TAVI) for Patients with severe aortic valve stenosis.

IN PROGRESS

WP2 Group: Laura Amato, Luciana Ballini, Massimo Brunetti, Roberto D'Amico, Marina Davoli, Luca De Fiore, Rossana De Palma, Eliana Ferroni, Marien Gonzalez Lorenzo, Nicola Magrini, Lorenzo Moja, Francesco Nonino, Salvatore Panico, Donato Papini, Elena Parmelli, Vanna Pistotti, Silvia Pregno, Carlo Saitto, Gianni Virgili, Gustavo Zanoli.

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DECIDE Developing and Evaluating GRADE Communication strategies to support Informed Decisions and practice based on Evidence

Work Package 2

Policymaker and manager focussed strategies for communicating evidence-based recommendations

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Developing a conceptual framework to support coverage decisions for vaccines adoption in Lombardy (Italy)

It aims to develop a transparent and comprehensive standard framework for the inclusion and prioritization of new vaccines in the regional immunization program. The framework should act as a guide to consistently inform policy makers in the Region of Lombardy. The research consists of three phases:

PHASE 1

Objective: To review the literature on decision-making coverage around the adoption of vaccines and to propose a transparent and comprehensive framework based on evidence-based criteria using the DECIDE approach.

Method: We systematically searched literature (MEDLINE, Embase, The Cochrane Library) and funding agency websites from 1990 to 2013. We included systematic reviews (SRs) and primary studies describing decisional supportive tools for community vaccine adoption and qualitatively summarised the reports. The proposed dimensions were extracted and compared to recognize similar ones. The critical dimensions were integrated so as to generate a framework that guides decisions on vaccine adoption.

Results: 14 studies (5 SRs and 9 primary studies) were included, all published after the year 2000. The conceptual models featured broad differences in the terminology used, even though the construct of the dimensions appeared to be largely overlapping. The most frequent dimensions were "burden of disease," "vaccine characteristics," and "economic considerations."

We identified 10 dimensions proposed in the studies included, all of which resembled those of the DECIDE framework. We then linked the 10 dimensions to those of DECIDE. At the same time, the studies were used to define proposal criteria useful to describe the dimensions. In table 1, we present a description of the dimensions of the framework, the related questions and the number of criteria proposed.

Table 1

DIMENSIONS	DESCRIPITON	QUESTION	CRITERIA PROPOSED
Burden of disease	Description of epidemiologic and clinical features of the disease/condition of interest in terms of seriousness of consequences.	Is the vaccination a priority?	**27 criteria**
Vaccine characteristics and impact of immunisation programme	Description of the effect and adverse events of the vaccine using the GRADE method. Overall quality of the available evidence of effects across all of the outcomes that are critical to making a decision.	What is the net benefit of the vaccination? How confident are we about the net benefit of the vaccination?	**23 criteria**
Values and preferences	Consideration of values and preferences of patients/care givers about the balance between desirable and undesirable effects of the vaccine.	What is the appreciation and value of the vaccination in the population?	**4 criteria**
Resource use	All the information about costs and use of resources.	What are the costs of the vaccination and are they limited compared to the benefits?	**9 criteria**
Equity	Impact on health inequities.	Would some part of the population taking advantage from the vaccination compared to other groups?	**7 criteria**
Feasibility	Information on applicability, professionals' acceptability, possible barriers, impact on professional style and type of practice, and the organisational impact.	Which vaccination barriers or facilitators act at the system level?	**11 criteria**

PHASE 2

Objective : To share and validate the framework proposed using a Delphi method.

Method: A total of 59 participants from multidisciplinary areas, including policy-makers, managers, methodologists, general practitioners, paediatricians, infectious disease specialists, drug policy experts, economists, epidemiologists and members of patient associations were invited by e-mail to participate in the Delphi study. A questionnaire was constructed based on DECIDE's dimensions and criteria identified by the authors in phase 1 of the current project. This resulted in 81 structured questions asking about the relevance of each criteria. Participants were requested to rate these factors on a 9-point Likert scale ranging from 0 (not at all important) to 9 (extremely important). We then conducted a three-round Delphi consensus process through Internet and a discussion group.

Results: A total of 46 participants accepted the invitation. The final framework consisted of 6 dimensions and 80 criteria. The results of Delphi rounds are presented in the figure bellow.

PHASE 3

Objective: To study the feasibility of the developed framework in regards to a vaccine.

Method: This phase will be divided into two parts. 1) Developing a framework: From the criteria considered to be relevant in phase 2, we will complete the information corresponding to each dimension ("Burden of disease", "Vaccine characteristics and impact of immunisation programme", "Values and preferences", "Resource use", "Equity" and "Feasibility"), focusing on a target vaccine. 2) Delphi method (round 4): We will send the framework to the participants of the Delphi in order to achieve a consensus for the final framework.

This project is conducted by the University of Milan in collaboration with WP2 of the DECIDE Project and supported by a grant from the Region of Lombardy, Italy.

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 258583.

Regione Lombardia

Direzione Generale Salute, UO Governo della Prevenzione e Tutela Sanitaria, Regione Lombardia

DECIDE
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Silvia Pregno*, Massimo Brunetti*, Anita Chiarolanza* on behalf of WP2 group.

*Modena Local Health Service Trust (Italy)

Using DECIDE for coverage decision making in the real world: the experience of the Modena Local Health Service Trust

The role of medical devices in health care is crucial. Many of them are highly innovative and the regulatory system for the placing on the market is much less regulated than for drugs. These two characteristics of medical devices are the basis of the particular challenges in coverage decision.

In November 2013, the Chief Executive of Modena Local Health Service Trust (Italy) decided to use the 'Evidence to Decision Coverage' framework (EtCD) produced by WP2 of the DECIDE project, focused on evidence-based policy, in order to make decisions with respect to the coverage of medical devices in scope of the Medical Device Commission, which is made up of a multidisciplinary working group that acts on behalf of the Chief Executive of Local Health Service Trust .

This decision aims to increase the use of evidence-based interventions in a sustainable way and to reduce the use of interventions where benefits are uncertain and to increase transparency in the medical devices decision process, also in accordance with Law 190/2012 on the transparency, which aims to prevent corruption in the NHS.

To date, we have applied the EtCD to the robot-assisted surgery, the local hemostatic surgical sealants and MRI compatible pacemaker. In the coming months we will apply it on pacemaker for remote monitoring, BAHA hearing aids and other surgical devices.

The EtCDs were produced by a methodologist, an health economist, both expert in GRADE methodology and participant with WP2, and an economist expert in research on equity in National Health Systems.

What we learned from this experience:

- **About EtCD drafting and contents**: there is lack of evidence and low or very low quality of evidence . Source of evidence most of the time are provided by medical devices industry.
- **About the acceptability and feasibility**: there is lack of evidence in order to understand local contest, and the need to draw information from current data, opinion of experts and practitioners and evaluation of the health system locally
- **About the equity information**: there is lack of evidence, the need to find epidemiological data on socio-cultural characteristics of the local population and the assessment of the local organization of the health system . In both cases, the retrieval of this information requires time and a specific skills
- **About the resource use**: the method allow to overcome traditional problems of economic evaluation, showing difference of resources data and effectiveness in a way that is more transparent and reproducible compared to traditional economic evaluation
- **About coverage decision**: policy makers always decided to cover conditionally, in the context of a clinical trial, generally because of the paucity of evidence about benefits and harms and considering possible inequity in the use of the device
- **About policy makers satisfaction in receiving information through the EtCD framework**: high degree of satisfaction with this tool, which they regard as a quick reference, full of useful information, and transparent.

References:

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